

REMARKS

The Office Action dated July 27, 2009 has been received and reviewed. Claims 58 to 96 are pending in the application. Claims 58-96 are rejected.

Rejection under 35 USC 112

Claims 78-80 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 recited the limitation "the iodine complex" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 78 is currently amended to establish dependency to claim 61. Claim 61 recites a group that includes an "iodine complex".

Claim 79 recited the limitation "the chlorhexidine" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 79 is currently amended to establish dependency to claim 61. Claim 61 recites a group that includes "chlorhexidine".

Claim 80 recites the limitation "the chlorhexidine salt" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 80 is currently amended to establish dependency to claim 79. Claim 79 recites a "chlorhexidine salt".

The amendments to claims 78-80 render moot the rejection under 35 USC 112, second paragraph. Withdrawal of the rejection of claims 78-80 under 35 USC 112, second paragraph, is hereby requested.

Rejection under 35 USC 103

Claims 58-60, 62-70, 72, 76, 77, 81, 83-89 and 91-96 are rejected under 35 USC 103(a) as being unpatentable over Crosby et al. (U.S. Provisional Application Publication No. 2002/0076258) in view of Pettersson et al. (WO 99/03677).

The Patent Office appears to equate the Applicant's "container" with the hollow handle 20 that is described in paragraph 30 of Crosby et al. The Patent Office asserts that paragraph 30 of Crosby et al. also discloses that the container "further comprises at least one barrier layer made of made of polyethylene terephthalate (PET)". Applicant cannot find a reference to the alleged "barrier layer" in paragraph 30. Applicant

requests that the Patent Office recite the part number and/or the sentence in paragraph 30 of Crosby et al. that describe the alleged “barrier layer”.

As applied in the rejection of claim 58, the Patent Office alleges that Crosby et al. discloses a “container” comprising a “barrier layer”, as claimed, and that Pettersson et al. discloses using a sterilizing gas to provide the container with a sterile exterior. As discussed above, Crosby does not disclose a container comprising a “barrier layer”. Therefore, the modification of the article of Crosby et al. with the process of Pettersson et al., as applied in the rejection, does not contain all elements of claim 58. Withdrawal of the rejection of claim 58 under 35 USC 103(a) as being unpatentable over Crosby et al. (U.S. Provisional Application Publication No. 2002/0076258) in view of Pettersson et al. (WO 99/03677) is hereby requested.

Claim 59 is patentable for at least the reasons discussed above. Claims 59, 60, 62-70, 72, 76, and 77 each add additional features to claim 59. Therefore, claims 59, 60, 62-70, 72, 76, and 77 are likewise patentable. Therefore withdrawal of the rejection of claims 59, 60, 62-70, 72, 76, and 77 under 35 USC 103(a) as being unpatentable over Crosby et al. (U.S. Provisional Application Publication No. 2002/0076258) in view of Pettersson et al. (WO 99/03677) is hereby requested.

Independent claims 58, 81, and 89, each of which recite a container and/or a barrier layer with substantially limited permeability to ethylene oxide. The Patent Office asserts that Crosby disclose “a container made of PET, which is inherently and necessarily substantially impermeable to ethylene oxide as the phrase ‘substantially impermeable’ is defined in the disclosure” (emphasis added).

Applicant does not dispute that Crosby discloses an article (hollow handle 10) that is formed, inter alia, from PET. However, Crosby is silent regarding the ethylene oxide-permeability properties of the article. Applicant request that the Patent Office show evidence that the article of Crosby is substantially impermeable to ethylene oxide.

Pettersson discloses a laminate structure comprising an outer layer of PET, the material the Patent Office asserts is “inherently and necessarily impermeable to ethylene oxide”. However, Pettersson attributes the ethylene oxide impermeability of the laminate as due to the intermediate layer containing silicon oxide, as shown in the following excerpt from page 3, lines 4-14:

There is no disclosure in the art, though, of the effectiveness of such silicon oxide-containing laminates as barriers to ethylene oxide gas. Moreover, there is no disclosure of such laminates being relatively inert to ethylene oxide gas such that the formation of 2-chloroethanol is kept to an acceptable level or of such laminates not trapping ethylene oxide gas.

It has surprisingly been found by the Applicants that a laminate having an inner layer which contains a polyolefin, an outer layer which contains a polyester, a polyolefin or a polyamide and an intermediate layer which contains a silicon oxide has a low permeability to ethylene oxide gas and is relatively unreactive with ethylene oxide gas. Such a laminate is referred to in the following Section as a "laminate of the type defined".

Furthermore, Table 3 (Tube Nos. 1 and 5) of the instantaneous application shows that two containers with similar, but non-identical, PET-containing constructions (HDPE/CXA/PET) can have significantly different properties with respect to ethylene oxide permeability. Without being bound by theory, Applicants point out that, with respect to barrier layers, the differences in ethylene oxide permeability may be related to the thickness and/or crystallinity of the materials.

In summary, Applicant has shown that all articles formed from PET are not necessarily and inherently substantially impermeable to ethylene oxide. The Patent Office has not met the burden of showing that the particular construction of Crosby fulfills the requirements of independent claims 58, 81, and 89. MPEP 2112 sets forth the burden of proof for the requirements of a rejection based upon inherency:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

The Patent Office has not met its burden of proof to show the inherency ethylene oxide impermeability in the article of Crosby. Therefore, the rejection of claims 58, 81, and 89

under 35 USC 103(a) as being unpatentable over Crosby et al. (U.S. Provisional Application Publication No. 2002/0076258) in view of Pettersson et al. (WO 99/03677) is improper and should be withdrawn.

In summary, claim 58 is patentable over Crosby et al. in view of Pettersson et al. for at least the reasons discussed above. Claims 59, 60, 62-70, 72, 76, and 77 each add additional features to claim 58 and are likewise patentable over Crosby and Pettersson. Claim 81 is patentable over Crosby et al. in view of Pettersson et al. for at least the reasons discussed above. Claims 83-88 each add additional features to claim 81 and are likewise patentable over Crosby and Pettersson. Claim 89 is patentable over Crosby et al. in view of Pettersson et al. for at least the reasons discussed above. Claims 91-96 each add additional features to claim 89 and are likewise patentable over Crosby and Pettersson.

Claim 61 is rejected under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claim 58 above and further in view of Fendler et al. (U.S. Patent No. 6,333,039).

Claim 61 recites the feature of a container comprising a barrier layer that is substantially impermeable to gaseous ethylene oxide. Crosby et al. does not teach or suggest a container comprising a barrier layer that is substantially impermeable to gaseous ethylene oxide, as discussed above. Furthermore, the Patent Office has not met the burden of proof to assert that the alleged container of Crosby is inherently substantially resistant to ethylene oxide, as discussed above. Fendler et al. does not teach or suggest a container that is substantially impermeable to gaseous ethylene oxide or that the container comprises a barrier layer that is substantially impermeable to gaseous ethylene oxide. The modification of Crosby et al. with Pettersson et al. and Fendler et al. does not result in all of the elements of claim 61. Therefore, the rejection of claim 61 under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claim 58 above and further in view of Fendler et al. (U.S. Patent No. 6,333,039) is improper and should be withdrawn.

Claims 71 and 73-75 are rejected under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claim 58 above and further in view of Langley (U.S. Patent No. 5,560,974).

Independent claim 73 recites a container that is substantially impermeable to ethylene oxide. The Patent Office asserts that Crosby disclose "a container made of PET, which is inherently and necessarily substantially impermeable to ethylene oxide as the phrase 'substantially impermeable' is defined in the disclosure" (emphasis added). Applicant disagrees for at least the reasons discussed above relative to independent claims 58, 71, and 89.

Claims 58 and 73 are patentable over Crosby et al. and Pettersson et al. for at least the reasons discussed above. Langley does not teach or suggest a container that is substantially impermeable to gaseous ethylene oxide. The modification of Crosby et al. with Pettersson et al. and Langley does not result in all of the elements of claim 73. Therefore, the rejection of claim 73 under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claim 58 above and further in view of Langley (U.S. Patent No. 5,560,974) is improper and should be withdrawn.

Claim 71 adds additional features to claim 58 and is likewise patentable over Crosby and Pettersson in view of Langley. Claims 74 and 75 each add additional features to claim 73 and are likewise patentable over Crosby and Pettersson in view of Langley.

Claims 78, 79, 82 and 90 are rejected under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claims 58 and 81 above, and further in view of Hoang et al. (U.S. Patent No. 5,607,699).

Claims 58, 81, and 89 are patentable over Crosby et al. and Pettersson et al. for at least the reasons discussed above. Hoang et al. does not teach or suggest a container that is substantially impermeable to gaseous ethylene oxide. Therefore, the modification of Crosby et al. with Pettersson et al. and Hoang et al. does not result in all of the elements of claim 58, 81, 89, or the corresponding dependent claims 78, 79, 82, and 90. The rejection of claims 78, 79, 82, and 90 under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claim 58 above and further in view of Hoang et al. (U.S. Patent No. 5,607,699) is improper and should be withdrawn.

Claim 80 is rejected under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claim 58 above, and further in view of Behrends et al. (U.S. Application Publication No. 2001/0036963).

Claim 58, from which claim 80 depends, is patentable over Crosby et al. and Pettersson et al. for at least the reasons discussed above. Behrends et al. does not teach or suggest a container that is substantially impermeable to gaseous ethylene oxide or that the container comprises a barrier layer that is substantially impermeable to gaseous ethylene oxide. Therefore, the modification of Crosby et al. with Pettersson et al. and Behrends et al. does not result in all of the elements of claim 58. Claim 80 adds additional features to claim 58. Therefore, the rejection of claim 80 under 35 USC 103(a) as being unpatentable over Crosby ('258) in view of Pettersson et al. ('677) as applied to claim 58 above and further in view of Behrends et al. (U.S. Application Publication No. 2001/0036963) is improper and should be withdrawn.

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 736-7430. A notice of allowance for all pending claims is respectfully solicited.

Respectfully submitted,



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